

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

This Document Relates to:
All Cases

MDL No. 1:13-md-2419-RWZ

**MEMORANDUM OF LAW IN SUPPORT OF
MOTION OF THE CHAPTER 11 TRUSTEE FOR A PROTECTIVE ORDER
PURSUANT TO FED. R. CIV. P. 26(c) AND 45(c) PRECLUDING THE TENNESSEE
CLINIC DEFENDANTS FROM CONDUCTING A DEPOSITION OF NEW ENGLAND
COMPOUNDING PHARMACY, INC. PURSUANT TO FED. R. CIV. P. 30(b)(6)**

Pursuant to Rules 26(c) and 45(c) of the Federal Rules of Civil Procedure, Paul D. Moore, the Chapter 11 Trustee (the “Trustee”) for the Chapter 11 estate of New England Compounding Pharmacy (“NECC” or the “Debtor”), seeks the entry of an order precluding the Tennessee Clinic Defendants from conducting their proposed deposition of NECC pursuant to the Fed. R. Civ. P. 30(b)(6) subpoena they served on the Trustee.

I. FACTUAL BACKGROUND

A. THE CHAPTER 11 PROCEEDING AND THE APPOINTMENT OF THE TRUSTEE

On December 21, 2012 (the “Petition Date”), the debtor, New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Company (“NECC” or the “Debtor”), filed a voluntary petition for relief pursuant to chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (the “Bankruptcy Court”).

On January 24, 2013, the Bankruptcy Court entered an order [Docket No. 92] ordering the appointment of a chapter 11 trustee pursuant to section 1104(a) of the Bankruptcy Code.

On January 25, 2013 (the “Appointment Date”), the United States Trustee (the “UST”) filed an Application for and Certificate of Appointment of Chapter 11 Trustee [Bankruptcy Docket No. 98] (the “UST Application”) requesting the Bankruptcy Court’s approval of my appointment as Chapter 11 Trustee. The UST Application was granted by order of the Bankruptcy Court [Bankruptcy Docket No. 99] entered the same day. Thereafter, on February 1, 2013, I filed the Verified Statement Pursuant to Rule 2007.1 of Paul D. Moore in Support of Application for and Certificate of Chapter 11 Trustee [Bankruptcy Docket No. 111] (the “Statement”).

B. EVENTS PRECIPITATING THE CHAPTER 11 CASE

Prior to the Petition Date, NECC operated as a compounding pharmacy. Beginning in September 2012, reports began to surface of several patients who contracted fungal meningitis (the “Outbreak”) after receiving injections of preservative-free methylprednisolone acetate (“MPA”) compounded by NECC. An investigation was initiated by the Massachusetts Department of Public Health (“MDPH”) and, two days later, on September 26, 2012, NECC issued a voluntary recall of three suspect lots, containing approximately 18,000 doses of MPA that NECC had distributed to hospitals, clinics and doctors’ offices, and were administered to approximately 14,000 patients. The Centers for Disease Control and Prevention (“CDC”) reported that, as of October 23, 2013, 64 people had died and 751 individuals had fallen ill.³

In response to the October 2, 2012 findings from the United States Food and Drug Administration (“FDA”) and the MDPH, the Massachusetts Board of Registration in Pharmacy (the “Board”) voted to request a voluntary surrender of NECC’s pharmacy license.

³ The CDC has not updated the case counts since October 23, 2013 and indicates that further updates to the case counts are not anticipated.

NECC surrendered its license effective at noon on October 3, 2012, and further instituted a voluntary recall of all of its intrathecal medications, which are designed for injection near the spinal cord or brain. The FDA and the CDC recommended that all health care providers cease using, and remove from inventory, any NECC products. At the behest of the MDPH, NECC issued an immediate recall of all of its products. There remain ongoing proceedings to revoke or otherwise take action against the licenses of NECC's pharmacists. Approximately three months prior to the Petition Date, NECC suspended the operation of its business. NECC also surrendered its Massachusetts pharmacy license and laid off most of its employees. The MDPH has temporarily barred former pharmacists for NECC from practicing pharmacology.

On the Petition Date, NECC filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code. NECC has stated that it initiated this Chapter 11 Case in response to the volume and wide geographic distribution of the lawsuits with which it was confronted. The Outbreak has resulted in thousands of claims from personal injury claimants against NECC and others. As of April 27, 2015, approximately 686 separate lawsuits had been joined in the MDL Proceeding pending before the Honorable Rya W. Zobel, United States District Court Judge, in the MDL Court. Approximately 3,770 proofs of claims have been filed in NECC's Chapter 11 Case, approximately 3,500 of which are for damages for death or personal injuries resulting from the Outbreak.

C. STATUS OF NECC AT THE TIME OF THE TRUSTEE'S APPOINTMENT

At the time of the Trustee's appointment, NECC had ceased operations for 4 months. All employees had resigned or had been terminated. Prior to his appointment, the Trustee had absolutely no involvement with, or knowledge of, NECC or its operations.

The Trustee's goal was to marshal all of the assets of NECC's chapter 11 estate for eventual distribution to creditors under chapter 11 of the Bankruptcy Code. In fact, the Trustee,

together with the Official Committee, filed the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. with the Bankruptcy Court. The Bankruptcy Court has scheduled a confirmation hearing for May 19, 2015.

D. THE FEDERAL INDICTMENTS

On December 16, 2014, a federal grand jury sitting in the District of Massachusetts returned a 131-count indictment against 14 individuals. Barry J. Cadden (a former director and President of NECC and former Head Pharmacist and Director of Pharmacy of NECC), Gregory A. Conigliaro (a former director and Treasurer, Secretary, and Vice President of NECC) and Carla R. Conigliaro (a former director of NECC).

The primary counts in the indictment charged certain of the indicted individuals with racketeering, in violation of 18 U.S.C. § 1962(c) (Count 1), Racketeering Conspiracy, in violation of 18 U.S.C. § 1962(d) (Count 2) and Conspiracy to Defraud the United States, in violation of 18 U.S.C. § 371 (Count 3). *United States v. Cadden, et al.*, Criminal Case No. 14-10363-RGS.

Due to the criminal proceedings, none of these individuals is available to testify in any civil proceeding. None will consent to testify on NECC's behalf in any civil proceeding.

II. THE TRUSTEE'S LACK OF KNOWLEDGE AND THE UNAVAILABILITY OF ANY WITNESS TO TESTIFY ON BEHALF OF NECC WITH REGARD TO THE TOPICS IDENTIFIED IN THE RULE 30(B)(6) DEPOSITION NOTICE

The Trustee has reviewed the Rule 30(b)(6) deposition notice and the list of topics on which examination is requested (the "Deposition Topics"). He has no personal knowledge of any of the Deposition Topics. Further, to the extent that he has any knowledge, such knowledge is protected from disclosure by the attorney-client privilege and the work product doctrine. NECC has no officers, director, managing agents or others who have knowledge of the Deposition Topics and who will consent to testify on NECC's behalf.

III. ARGUMENT

A. **THE COURT SHOULD ENTER A PROTECTIVE ORDER PRECLUDING THE TENNESSEE CLINIC DEFENDANTS FROM PROCEEDING WITH THE RULE 30(B)(6) DEPOSITION.**

Rule 26(b)(2)(C) provides that discovery shall be limited by the court if it determines that:

(i) the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

In this case, a protective order is appropriate under *each* of the subsections of this rule.

To assert their comparative fault defense, the Tennessee Clinic Defendants do not need anywhere near the volume of information they seek from the Trustee. According to their counsel, the plaintiffs in their cases have agreed to stipulate that NECC distributed the product administered by the Tennessee Clinic Defendants. In addition, the Trustee has already made available in the document Repository maintained by the Plaintiffs' Steering Committee and available to the Tennessee Clinic Defendants and all parties to the MDL, over 32,000 pages of documents which are responsive to the subpoena and has agreed to provide additional relevant documents not already in the repository.

Third parties have actual knowledge of some of the Deposition Topics. Notably, the Tennessee Clinic Defendants have already served a subpoena upon the FDA. The Tennessee Clinic Defendants have identified 15 former employees of NECC (*see, e.g.*, Document Request No. 1, which identifies 15 former NECC employees and seeks production of their personnel

files) who should have personal information relating to the Deposition Topics. In fact, they have noticed the depositions of Douglas Conigliaro, Carla Conigliaro, Gregory Conigliaro and Lisa Cadden, all of whom are identified the Tennessee Clinic Defendants Document Request No. 1.⁴ Similarly, while the Tennessee Clinic Defendants seek testimony from the Trustee relating to NECC's relationship with over 22 entities, representatives of the entities themselves are best suited to provide testimony relating to relationships with NECC as to which the Trustee has no knowledge. The Tennessee Clinic Defendants have, in fact, noticed the depositions of representatives of two of those entities: Ameridose, LLC and GDC Properties, LLC.

In light of: (1) the plaintiffs' willingness to stipulate that NECC distributed the product administered by the Tennessee Clinic Defendants; (2) the document production from the Trustee; and (3) information available from the FDA and others, the Tennessee Clinic Defendants are able develop the information they reasonably need to argue that NECC bears responsibility for supplying the product they administered. Forcing the Trustee to appear and assert privilege, or to say he has no personal knowledge of the Deposition Topics does not warrant "the burden or expense of the proposed discovery" taking into account "its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, and the importance of the proposed discovery in resolving the issues."

To comply with the notice, the Trustee would have to reach out to the same third parties available to the Tennessee Clinic Defendants (*e.g.*, the FDA) and thereafter educate a witness to testify on NECC's behalf. In essence, the Tennessee Clinic Defendants are seeking to delegate to the Trustee their own pretrial investigation. This Court should not permit them to shift this financial burden to the NECC estate. Every dollar spent performing an investigation on the

⁴ To the extent that third parties with knowledge refuse to cooperate due to Fifth Amendment concerns, they are *equally* unavailable to the Tennessee Clinic Defendants and the Trustee.

Tennessee Clinic Defendants’ behalf (which they are fully capable of performing themselves) results in one less dollar available for distribution to NECC’s creditors.

This case is similar to *FDIC v. Wachovia Ins. Servs.*, 2007 U.S. Dist. LEXIS 62538 (D. Conn. Aug. 27, 2007). In that case, the FDIC, in its capacity as a receiver of a failed bank, filed a civil breach of contract and negligence action against Wachovia. Wachovia served FDIC with a Rule 30(b)(6) deposition notice which identified twenty-seven areas of inquiry (the Deposition Notice identifies thirty-one) and demanded production of thirteen different categories of documents. FDIC sought successfully a protective order.

The court noted that the FDIC receiver, was never involved in the matters on which examination was requested. As a consequence, the Rule 30(b)(6) notice was overbroad and burdensome. Although the court recognized the fact “[t]hat the plaintiff [*i.e.*, the FDIC] had no involvement with [the failed bank] before its failure does not, standing alone, relieve it of its obligation to designate a Rule 30(b)(6) deponent.” *Id.* at *5, the court noted that this lack of pre-receivership involvement warranted limiting the scope of the Rule 30(b)(6) deposition. *Id.* (“As plaintiff correctly points out, however, its lack of pre-failure involvement with [the failed bank] does bear upon the reasonableness of the scope of the discovery that has been requested by Wachovia.”) (emphasis added); *see also FDIC v. Brudnicki*, 2013 U.S. Dist. LEXIS 154908, *7 (N.D. Fla. Oct. 29, 2013)(“While the FDIC’s lack of personal knowledge of the pre-failure events occurring at the failed bank does not relieve the FDIC of its obligations to designate and produce a Rule 30(b)(6) deponent, the FDIC’s lack of pre-failure involvement with the failed bank does bear upon the reasonableness of the scope of discovery”).

The court stated, “it is difficult to imagine how Wachovia’s Rule 30(b)(6) notice could be more broadly drawn.” *Id.* at *8 (noting that the notice “seeks to burden the plaintiff with

educating representatives with respect to twenty-seven areas of inquiry (many of which are open ended) and with producing thirteen different categories of documents, many of which are of marginal, tangential, or dubious relevance.”). The court therefore determined that “to enforce this deposition notice would be abusive” and entered a protective order quashing the notice.

This case is no different. The Tennessee Clinic Defendants seek examination on thirty-one different topics from a Trustee who was appointed four months after NECC ceased operating. Further, in contrast to the *FDIC v. Wachovia* case, the Trustee is not a party to the lawsuit under which the Tennessee Clinic Defendants seek discovery. Moreover, the NECC estate (in contrast to the FDIC) has limited resources, and, if the Trustee is forced to accept the unreasonable burden of complying with the Deposition Notice, his compliance will come at the expense of NECC’s creditors and divide his efforts during the time when he and his counsel are fully engaged in preparing for the May 19, 2015 confirmation hearing.

B. THE COURT SHOULD QUASH THE DEPOSITION SUBPOENA

Fed. R. Civ. P. 45(d)(3)(A) states:

Rule 45. Subpoena

(d) Protecting a Person Subject to a Subpoena Enforcement.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

Discovery is not unlimited, and “fishing expeditions” are particularly curtailed by courts in the First Circuit. The First Circuit does not allow discovery that is unrelated to the claims, simply on speculation that something relevant will turn up. *Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 193 (1st Cir. 2001) (“we will not allow Signal to go on a ‘fishing expedition,’ with the mere ‘hope’ that it will obtain such information.”). The First Circuit limits “over-discovery,” holding that parties “ought not to be permitted to use broadswords where scalpels will suffice, nor to undertake wholly exploratory operations in the vague hope that something helpful will turn up.” *Mack v. Great Atl. & Pac. Tea Co.*, 871 F.2d 179, 187 (1st Cir. 1989).

Here, the Tennessee Clinic Defendants, under the guise of seeking discovery into comparative fault, have served an unreasonably burdensome Rule 30(b)(6) deposition notice on NECC.

The burden on the respondent must be balanced carefully. Under Rule 45, the Court must quash a subpoena that “subjects a person to undue burden.” Fed. R. Civ. P. 45(c)(3)(A). In making this determination, courts are required to balance the need for discovery against the burden imposed on the entity ordered to produce documents. Moreover, the status of an entity as a non-party is a factor that weighs against requiring discovery that burdens the respondent. The United States Court of Appeals for the First Circuit has held that a non-party has a different status, a different “set of expectations” that are “entitled to special weight.” *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998) (“Although discovery is by definition

invasive, parties to a lawsuit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs.”). Here, the burden of complying with the Deposition notice is unreasonable and is especially burdensome in light of the fact that NECC is a non-party.

This Court should quash the deposition subpoena.

IV. CONCLUSION

For the preceding reason, this Court should enter a protective order precluding the Tennessee Clinic Defendants from proceeding with the Rule 30(b)(6) deposition and should enter an order quashing the deposition subpoena under Rule 45(c).

Dated: May 1, 2015
Boston, Massachusetts

Respectfully submitted,

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Certificate of Service

I, Michael R. Gottfried, hereby certify that on this day, May 1, 2015, I caused a copy of the foregoing document, which was filed using this Court's ECF system, to be served electronically upon those parties registered to receive ECF service.

/s/ Michael R. Gottfried